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SERIAL NO. 10/821,125

PATENT APPLICATION

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

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| Appellant: | Favet et al. | Examiner: | Malamud, D. |
| Serial No.: | 10/821,125 | Group Art Unit: | 3766 |
| Filed: | April 8, 2004 | Docket No.: | GUID.119PA |
| Title: | IMPLANTABLE SUDDEN CARDIAC DEATH PREVENTION DEVICE WITH REDUCED PROGRAMMABLE FEATURE SET | | |

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Mail Stop Appeal Brief - Patents, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450, August 11, 2008.

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REPLY BRIEF

Mail Stop Appeal Brief - Patents
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Sir:

This Reply Brief is submitted pursuant to 37 C.F.R. § 41.41 in response to the Examiner's Answer dated 06/11/2008. This submission is within two months of the Examiner's Answer and is thus believed to be timely filed.

This paper does not unnecessarily duplicate all of the various required sections that were included in the Amended Appeal Brief filed on or about April 17, 2008. We also do not repeat here all of the arguments set forth in the Arguments section of the original Appeal Brief. Instead, this paper includes only those sections specified in MPEP § 1208 as appropriate for a Reply Brief, and the Arguments section herein is intended to address the new points raised in the Examiner's Answer.

No fee is believed to be due by the filing of this paper. If, however, this belief is incorrect, authority is given to charge/credit deposit account 50-3581 (GUID.119PA) any additional fees/overages in support of this filing.

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I. STATUS OF CLAIMS

Claims 1-68 remain pending. Each of the pending Claims 1-15 and 68 has been finally rejected by the Examiner's action dated March 23, 2007, from which Appellant appeals.

Claims 16-67 were withdrawn by the Examiner as being directed to non-elected inventions subject to a restriction requirement, which does not form part of this appeal.

Claim 68 was added in the Office action response filed January 25, 2007.

The pending Claims 1-15 and 68 under appeal may be found in the attached Claims Appendix.

II. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

- A. Claims 1-12 stand rejected under 35 U.S.C. §102(b) over *Gill* (U.S. Patent No. 5,074,301).
- B. Claims 13-15 and 68 stand rejected under 35 U.S.C. §103(a) over *Gill* (U.S. Patent No. 5,074,301).

III. ARGUMENT

Appellant maintains the traversal of each of the grounds of rejection. Appellant further maintains the arguments presented in the Amended Appeal Brief of April 17, 2008.

In response to the Examiner's Answer, Appellant offers the following additional arguments and observations.

A. Rebuttal of Examiner's Arguments Regarding The Rejection Under 35 U.S.C. §102(b) of Claims 1-12 Based on Gill.

One having ordinary skill in the art would not confuse Gill's conventional bradycardia pacing therapy with the claimed non-physiologic, life sustaining pacing therapy, regardless of whether the skilled artisan interpreted the claimed non-physiologic, life sustaining pacing therapy in the descriptive sense or as a specially defined term.

The Examiner's Answer states that:

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). (Page 8).

It appears that the Examiner is contending that Appellant is attempting to define a claim term "contrary to its ordinary meaning." The Examiner's analysis is off point because Appellant is not attempting to define a claim term to have a meaning contrary to its ordinary meaning.

The ordinary meaning of a non-physiologic, life sustaining pacing therapy is consistent with the portions of the Specification identified in the Appeal Brief. (e.g., see Specification, Page 20, Lines 15-18, stating "[i]n an embodiment in which asystole prevention pacing is also made available, the SCDP device 502 produces pacing pulses in accordance with a non-physiologic, life sustaining pacing therapy, such as pacing therapy

deliverable at a rate lower than a bradycardia pacing rate”). If the therapy is non-physiologic, then it is entirely consistent that it pace at a rate lower than a bradycardia pacing rate, understanding that conventional bradycardia pacing restores normal sinus rhythm. (See Col. 1, Line 68 – Col. 2, Line 2 of Gill describing “a bradycardia support system as well as a high energy shock system to revert ventricular tachycardia to normal sinus rhythm,” emphasis added; see also Col. 1, Lines 9-12 describing restoration of sinus rhythm).

The portions of the Specification were cited on pages 9-10 of the Amended Appeal Brief to show that to any extent that one having ordinary skill in the art were to not realize from the claim term alone that Gill’s bradycardia therapy does not correspond with a non-physiologic therapy, then the Specification would make clear that the claimed non-physiologic, life sustaining pacing therapy is not a bradycardia therapy. For example, the claimed non-physiologic, life sustaining pacing therapy is described in the Specification deliverable at a rate lower than a bradycardia pacing rate (Page 20, Lines 15-18 and Page 28, Line 26 – Page 19, Line 1).

The Examiner’s Answer contends that Page 20, Lines 15-18 of the Specification is indefinite and is merely a possible example of a non-physiologic, life sustaining pacing therapy (by use of the phrase “such as”). Appellant notes Page 28, Line 26 – Page 19, Line 1 of the Specification proves a more definite statement:

An SCDP device of the present invention can be programmed to detect cardiac asystole, such as may occur after delivery of a defibrillation therapy, and, in response, deliver a life sustaining, non-physiologic pacing therapy to terminate the detected cardiac asystole. The pacing therapy provides for delivery of pacing pulses at a rate substantially lower than a bradycardia pacing rate.

The Examiner’s Answer also notes a lack of pacing rate ranges on Page 20 of the Specification. (Page 9). The Specification lists ranges in connection with the above quotation regarding a non-physiologic, life sustaining pacing therapy. (Page 29, Lines 10-

12). A range is also provided in dependent claim 68, which depends from independent claim 1.

In conclusion, one having ordinary skill in the art would not understand Gill to teach the precise invention of claim 1, for at least the reason that Gill does not teach a non-physiologic, life sustaining pacing therapy.

Considering just the descriptive sense of the term non-physiologic pacing therapy, Gill teaches conventional bradycardia pacing after delivery of a cardioversion shock to restore sinus rhythm. Nothing from Gill's disclosure indicates that Gill's therapy would be life saving, yet not sustain physiologic function.

In view of the Specification, Gill's bradycardia pacing does not correspond to the claimed non-physiologic, life sustaining pacing therapy. For example, Appellant's Specification states that the non-physiologic, life sustaining "pacing therapy provides for delivery of pacing pulses at a rate substantially lower than a bradycardia pacing rate." (Page 28, Line 26 – Page 19, Line 1, as quoted above).

As such, Gill does not teach all elements of independent claim 1, and cannot anticipate this claim. Reversal of the rejection is respectfully requested.

B. Rebuttal of Examiner's Arguments Regarding The Rejection Under 35 U.S.C. §103(a) of Claim 68 Based on Gill.

The Examiner disagrees with Appellant's contention that the pacing rate range of claim 68 is not an optimization of Gill because the non-physiologic, life sustaining pacing therapy and Gill's bradycardia therapy have different goals. Gill describes bradycardia therapy that paces a heart back to sinus rhythm after tachyarrhythmia. (Col. 1, Lines 9-12; Col. 1, Line 68 – Col. 2, Line 2; and Fig. 4C). The claimed therapy purposefully diverges from physiologic sustaining pacing. Therefore they have different goals. It would not be obvious that optimization of Gill's therapy would lead to the same range as Appellant claims, as it would appear that optimization of a therapy to restore sinus rhythm would sustain physiologic function.


The claimed range is not taught or suggested by Gill. Therefore, Gill does not teach or suggest all elements of dependent claim 68 and reversal of the rejection of this claim is respectfully requested.

IV. CONCLUSION

In view of the foregoing arguments, as well as the arguments presented in the Appeal Brief, Appellant respectfully submits that the claimed invention is patentable over the cited references and that the rejections of claims 1-15 and 68 should be reversed. Appellant respectfully requests reversal of the rejections as applied to the appealed claims and allowance of the entire application.

Respectfully submitted,

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